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10/500,167	10/12/2004	Helen Lee	62130-0009	9058

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EXAMINER	
ARCHIE, NINA	

ART UNIT	PAPER NUMBER
1645	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/500,167	LEE ET AL	
	Examiner	Art Unit	
	Nina A. Archie	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 April 2008*.

2a)☒ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12 and 14-22* is/are pending in the application.

4a) Of the above claim(s) *7-9 and 18-22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6, 10-12, and 14-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This Office is responsive to Applicant's amendment and response filed 12-3-07 and 4-29-08. Claims 1-12 and 14-22 are pending. 1-4, 7, 9, 10, 14-17 have been amended. Claims 7-9 and 19-22 are withdrawn. Claim 13 has been cancelled.

Election/Restrictions

2. Applicant's election of species of Group I claims 1-12 and 14-17 in the response filed 4-29-08 is acknowledged.

Group I (claims 7-9) are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the response filed 4-29-08.

Objections/Rejections Withdrawn

3. In view of the Applicant's amendment and remark following objections are withdrawn.

a) Objection to claims 7-17 is withdrawn in light of applicant's amendment thereto and light of cancellation of claim 13.

b) Rejection of claims 1-6 under 35 U.S.C. 112, second paragraph, is withdrawn in light of Applicant's amendment thereto.

c) Rejection of claim 1 under 35 U.S.C. 102(b), page, 5 last paragraph is withdrawn in light of Applicant's amendment thereto and applicant's argument.

d) Rejection of claim 1, 4-6 under U.S.C. 103(a), pages 7-8 is withdrawn in light of Applicant's amendment thereto and applicant's argument.

Claim Rejections Maintained

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. The rejection of claims 1 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by Biswas et al. 1997, Journal of Clinical Microbiology 35, 1560-1564 is maintained for the reason set forth in the previous office action.

Applicant arguments:

On pages 4-5 of the Office Action, the examiner rejects claims 1 and 3 allegedly as being anticipated by Biswas et al. (1997, Journal of Clinical Microbiology 35, 1560-1564). The examiner believes that Biswas et al. teach a method for treatment of a human patient sample (cervical brush smears) (refers to page 1560 paragraph 1-3) for carrying out a diagnostic method on the sample for detection of an infectious agent (HPV-16 E5) (refers to page 1567 "Results section"), wherein the sample is an endocervical fluid sample or a vaginal fluid sample, which includes the step of carrying out the diagnostic method in the presence of DNase, wherein the DNase is present in an amount of 5U in 10 µl (refers to "Materials and Methods"). Applicants respectfully disagree with the examiner and clarify the cited reference in order to assist the examiner in distinguishing the claimed invention. Biswas et al disclosure relates to the detection of HPV-16 early gene transcription by RT-PCR. Cervical brush smears obtained from patients were analyzed. Before carrying out RT- PCR, the samples was incubated overnight with DNase I. RNA was then extracted with phenol-chloroform-isoamyl alcohol prior to ethanol precipitation with linear polyacrylamide as a carrier. As would be apparent to the skilled person, DNase I is removed from the RNA by this procedure. Consequently, the subsequent RT-PCR procedure disclosed in Biswas was not performed in the presence of DNase. Indeed, since RT-PCR involves the synthesis of DNA, it would be most undesirable for the RT- PCR procedure to be carried out in the presence of DNase. Consequently, there is no disclosure in Biswas et al of carrying out a diagnostic method in the presence of DNase.

Examiner's Response to Applicant's Arguments:

Examiner accepts Applicant's amendments and arguments. However they are not deemed persuasive. Examiner disagrees with Applicant's assertion that Biswas et al does not teach a method for preparing a human patient sample (cervical brush smears) (refers to page 1560 paragraph 1-3) for performing a diagnostic method on the sample for detection of an infectious agent (HPV-16 E5) (refers to page 1567 "Results section"), wherein the sample is an endocervical fluid sample or a vaginal fluid sample, wherein the method comprises the steps of: a) treating the sample to reduce an inhibitory effect of the sample on the diagnostic method; and b) performing at least one step of the diagnostic method in the presence of DNase, wherein the DNase is present in an amount of 5U in 10 µl (refers to "Materials and Methods").

Although Applicant states that Biswas et al disclosure relates to the detection of HPV-16 early gene transcription by RT-PCR. Cervical brush smears obtained from patients were analyzed. Before carrying out RT- PCR, the samples was incubated overnight with DNase I. RNA was then extracted with phenol-chloroform-isoamyl alcohol prior to ethanol precipitation with linear polyacrylamide as a carrier. As would be apparent to the skilled person, DNase I is removed from the RNA by this procedure. Consequently, the subsequent RT-PCR procedure disclosed in Biswas was not performed in the presence of DNase. Indeed, since RT-PCR involves the synthesis of DNA, it would be most undesirable for the RT- PCR procedure to be carried out in the presence of DNase. Consequently, there is no disclosure in Biswas et al of carrying out a diagnostic method in the presence of DNase.

The instant claimed invention is drawn to a method for preparing a human patient sample for performing a diagnostic method on the sample for detection of an infectious agent, wherein the sample is an endocervical fluid sample or a vaginal fluid sample, wherein the method comprises the steps of: a) treating the sample to reduce an inhibitory effect of the sample on the diagnostic method; and b) performing at least one step of the diagnostic method in the presence of DNase.

Therefore because the instant claims are directed to discussion above and more specifically it states in step b) performing at least one step of the diagnostic method in the presence of DNase, the limitation has been met. Biswas et al teach a method as set forth supra, and furthermore Biswas et al a method comprising human patient sample, wherein the DNase is present in an amount of 5U in 10 µl in the sample thus Biswas et al teach step b) performing at least one step of the diagnostic method in the presence of DNase.

As outlined previously, the instant claim is drawn to a method for preparing a human patient sample for performing a diagnostic method on the sample for detection of an infectious agent, wherein the sample is an endocervical fluid sample or a vaginal fluid sample, wherein the method comprises the steps of: a) treating the sample to reduce an inhibitory effect of the sample on the diagnostic method; and b) performing at least one step of the diagnostic method in the presence of DNase.

Biswas et al. teaches a method for treatment of a human patient sample (cervical brush smears) (see pg. 1560 paragraph 1-3) for carrying out a diagnostic method on the sample for detection of an infectious agent (HPV-16 E5) (see pg. 1567 "Results section"), wherein the sample is an endocervical fluid sample or a vaginal fluid sample, which includes the step of carrying out the diagnostic method in the presence of DNase, wherein the DNase is present in an amount of 5U in 10 µl (see “Materials and Methods”).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. The rejection of claims 1-2 are rejected 35 U.S.C. 103(a) as being unpatentable over Biswas et al 1997, Journal of Clinical Microbiology 35, 1560-1564 in view of Holt et al TWGDAM Validation May 2001 pgs. 66-67 are maintained for the reasons set forth in the previous office action.

Applicant arguments:

On pages 6-7 of the Office Action, the examiner rejects claims 1-2 under 35 U.S.C. 103(a) allegedly as being unpatentable over Biswas et al (1997, Journal of Clinical Microbiology 35, 1560-1564) in view of Holt et al. (TWGDAM Validation May 2001 pgs. 66-67). The examiner admits that Biswas does not teach DNase present in an amount of more than 0.5 µg/ml, preferably 0.5 to 100 µg/ml. However, the examiner believes that Holt et al teach partially degraded DNA samples from blood and saliva samples were prepared using 0.005 units/ml of DNase I. Regarding claim 3, reciting the amount of the DNase more than 0.5 µg/ml, preferably 0.5 to 100 µg/ml, the examiner asserts that, the differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. The examiner believes that it would have been prima facie obvious at the time the invention was made to modify the method of treatment in the presence of DNase as taught by Biswas et al to optimize the amount of

the DNase because Biswas et al and Holt et al teach treatment with DNase in bodily fluids. Applicants respectfully disagree with the examiner and refer to above clarification and arguments regarding Biswas et al Applicants indicate that Biswas et al. does not disclose performing a diagnostic method in the presence of DNase. Holt et al does not rectify the deficiencies of Biswas et al. accordingly, the combination of the cited disclosure of Biswas et al and Holt et al does not provide a method within the scope of amended claim 1 or dependent claim 2. Withdrawal of the obviousness rejection is therefore solicited.

Examiner's Response to Applicant's Arguments:

Examiner accepts Applicant's amendments and arguments. However Examiner disagrees with Applicant. Biswas et al teach a method for preparing a human patient sample for performing a diagnostic method in the presence of DNase as discussed above. Holt et al does rectify the deficiencies of Biswas et al because Holt et al teach DNA samples from blood and saliva samples prepared using 0.005 units/μl of DNase I. Furthermore as stated in the prior office action, A particular parameter must first be recognized as a result-effective variable, i.e., a variable, which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation. In re Antonie, 559 F.2d 618, 195 USPQ 6 (CCPA 1977). In the instant application, the amount of Holt et al. produced a recognized result. Therefore, determining other optimum or workable amounts is routine experimentation. Also one would have motivated at the time the invention was made to modify the method of treatment in the presence of DNase as taught by Biswas et al to optimize the amount of the DNase because Biswas et al and Holt et al teach treatment with DNase in bodily fluids.

As outlined previously, the instant claims are drawn to a method for preparing a human patient sample for performing a diagnostic method on the sample for detection of an infectious agent, wherein the sample is an endocervical fluid sample or a vaginal fluid sample, wherein the method comprises the steps of: a) treating the sample to reduce an inhibitory effect of the sample on the diagnostic method; and b) performing at least one step of the diagnostic method in the presence of DNase.

Biswas et al is relied up as set forth supra. However Biswas et al does not teach DNase present in an amount of more than 0.5 μg/ml, preferably 0.5 to I00 μg/ml.

Holt et al teach partially degraded DNA samples from blood and saliva samples were prepared using 0.005 units/μl of DNase I.

As to the limitation dependent claim 3, the DNase present in an amount of more than 0.5 μg/ml, preferably 0.5 to I00 μg/ml. According to section 2144.05 of the MPEP, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). See also *Peterson*, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages.")

A particular parameter must first be recognized as a result-effective variable, i.e., a variable, which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation. In re Antonie, 559 F.2d 618, 195 USPQ 6 (CCPA 1977). In the instant application, the amount of Holt et al. produced a recognized result. Therefore, determining other optimum or workable amounts is routine experimentation.

It would have been prima facie obvious at the time the invention was made to modify the method of treatment in the presence of DNase as taught by Biswas et al to optimize the amount of the DNase because Biswas et al and Holt et al teach treatment with DNase in bodily fluids.

New Grounds of Objections

Claims 10 is objected to because of the following informalities: As to claim 10, the claim contains the acronym PVA and PVP. While acronyms are permissible

shorthand in the claims, the first recitation should include the full recitation followed by the acronym in parenthesis. Appropriate correction is required.

New Grounds of Rejections

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1, 4-6, 10-12, and 14-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sheiness et al US Patent No. 5,776,694 Date July 7, 1998 in view of Holt et al TWGDAM Validation May 2001 pgs. 66-67.

Claims 1, 4-6, 10-12, and 14-17 are drawn to a method for preparing a human patient sample for performing a diagnostic method on the sample for detection of an infectious agent, wherein the sample is an endocervical fluid sample or a vaginal fluid sample, wherein the method comprises the steps of: a) treating the sample to reduce an inhibitory effect of the sample on the diagnostic method; and b) performing at least one step of the diagnostic method in the presence of DNase.

Sheiness et al teach a method and kit for selective detecting a microorganism in vaginal samples associated with vaginal disorders obtained from a human patient (see abstract, column 39 lines 25-27, columns 23-24). Thus Sheiness et al teach a method for preparing a human clinical sample for performing a diagnostic method on the sample for detection of an infectious agent, wherein the sample is an endocervical fluid sample or a vaginal fluid sample, wherein the method comprises the steps of: a) treating the sample to reduce an inhibitory effect of the sample on the diagnostic method. Sheiness et al teach a method, wherein the sample is treated with an oxidizing agent, wherein the oxidizing agent is hydrogen peroxide (H202), wherein a working concentration of hydrogen peroxide is of 0.5% to 3% w/v specifically 1.8% (see Example 7), wherein the sample is treated with PVP, further comprising a working of concentration of 0.02%(w/v) (see Materials). Sheiness et al teach that the nucleic acid of the microorganism is usually a polynucleotide with an average length ranging from about 20 to about 20,000 bases or nucleotides in length (see column 20 lines 6-10). It is defined in the art that 1 amino acid is equal 110 Dalton. Thus Sheiness et al teach a method wherein the sample has an average molecular weight between 20 and 25 kDa. Sheiness et al teach that patient samples may be collected, processed and used in medical practioner's office, hospital, etc. (see example 6 and abstract) thus Sheiness et al teach a method, wherein the human patient sample is obtained as a self-collected vaginal swab sample, wherein the method is for detection of Chlamydia trachomatis (see column 32 line 5 and column 19 lines 25-30, and column 12), wherein the patient sample is a self-collected vaginal swab sample and the method is for detection of chlamydia trachomatis, wherein the method is a dipstick method (see column 7 lines 35-67, column 18-19, column 24 lines 55-60, table 2).

Sheiness et al is relied up as set forth supra. However Sheiness et al does not teach a method step b) performing at least one step of the diagnostic method in the presence of DNase, wherein the sample is treated with PVP at a working concentration between 0.2% and 2% w/v.

As to the limitation dependent claim 12, the claim states said recitation, "wherein the sample is treated with PVP at a working concentration between 0.2% and 2% w/v". According to section 2144.05 of the MPEP, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). See also *Peterson*, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages.") A particular parameter must first be recognized as a result-effective variable, i.e., a variable, which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation. In re Antonie, 559 F.2d 618, 195 USPQ 6 (CCPA 1977).

Therefore, although the reference does not teach the specific concentration in the method as claimed. The amount of a specific concentration in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Thus, optimization of general conditions is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of concentration would have been obvious at the time of applicant's invention.

Holt et al teach partially degraded DNA samples from blood and saliva samples were prepared using 0.005 units/μl of DNase I.

It would have been prima facie obvious at the time the invention was made incorporate DNase as taught by Holt et al into the method for preparing a human patient sample as taught by Sheiness et al because Sheiness et al and Holt et al teach treatment with DNase in bodily fluids.

Citation of Relevant Art

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Schuster et al. US Patent No. 4,059,404 Date November 22, 2007 teaches an elongated stick comprising a swab that can be made of a textile fiber material, e.g., polyvinyl alcohol and method of taking cell smears for diagnostic examination.

Status of the Claims

9. No claims are allowed.

Claims 1-6, 10-12, and 14-17 are rejected.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nina A. Archie whose telephone number is 571-272-9938. The examiner can normally be reached on Monday-Friday 8:30-5:00p.m..

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nina A. Archie whose telephone number is 571-272-9938. The examiner can normally be reached on Monday-Friday 8:30-5:00p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner supervisor, Shanon Foley can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nina A Archie/
Examiner, Art Unit 1645
/N. A. A./

Examiner, Art Unit 1645

Nina A Archie
Examiner
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REM 3B31

/Mark Navarro/

Primary Examiner, Art Unit 1645